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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,245	11/07/2001	Alexander K. Mills	WT-02-004C	6976

7590

04/02/2003

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EXAMINER

KREMER, MATTHEW J

ART UNIT

PAPER NUMBER

3736

DATE MAILED: 04/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

**Office Action Summary**

Application No.

10/008,245

Applicant(s)

MILLS, ALEXANDER K.

Examiner

Matthew J Kremer

Art Unit

3736

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 7-52 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 53 and 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>2</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

1. This application contains claims directed to the following patentably distinct species of the claimed invention:

Group I (claims 1-6, 53, and 55) is drawn to a method for determining the concentration of a blood constituent while varying the volume of blood;

Group II (claims 7, 17-18, and 30-52) is drawn to a method for determining a cardiac characteristic;

Group III (claims 8-16) is drawn to a method for determining the concentration of a blood constituent by varying the volume of blood using two probes;

Group IV (claims 19-25) is drawn to a method for determining the pH of blood;

Group V (claim 29) is drawn to a method for determining a chemical analyte using a tissue probe comprising a film containing a known concentration of the analyte;

Group VI (claim 54) is drawn to a method for determining the concentration of a blood constituent by varying the saturation of blood; and

Group VII (claim 26-28) is drawn to a method for determining the concentration of a blood constituent by determining the arterial and venous oxygen saturation.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

2. During a telephone conversation with Ralph C. Francis on 3/21/2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, 53 and 55. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-6, 53, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,638,816 to Kiani-Azarbayjany et al. Kiani-Azarbayjany et al. teaches a method of determining blood glucose using at least two emitters (column 7, lines 28-31 of Kiani-Azarbayjany et al.), at least two detectors (column 11, lines 37-38 of Kiani-Azarbayjany et al.), and a device for changing the volume of blood in the finger (column 6, lines 40-55 of Kiani-Azarbayjany et al.). The blood volume modulation device would change the path length of the wavelengths promulgated through the tissue. Also, measurements are taken throughout the blood volume modulation. (column 15, lines 18-36 of Kiani-Azarbayjany et al.). In regard to claim 2, hemoglobin is determined. (column 16, lines 15-54 of Kiani-Azarbayjany et al.). In regard to claim 3, the method can be used to determine venous oxygen saturation. (column 19, lines 19-23 of Kiani-Azarbayjany et al. and U.S. Patent 5,632,272 to Diab et al.). In regard to claim 4, the blood can be arterial or venous. (column 4, lines 43-49 of Kiani-Azarbayjany et al.). In regard to claim 5, the method includes determining the concentration of the constituent by comparing the radiation path length multiplied by the determined concentration. (column 16, line 15 to column 17, line 2 of Kiani-Azarbayjany et al.). In regard to claims

6 and 55, multiple light emitters at different wavelengths and detectors are used.  
(column 7, lines 28-31 and column 11, lines 37-38 of Kiani-Azarbayjany et al.).

### ***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,827,181 to Dias teaches a method of determining a blood constituent which involves a first radiation emitter, a first radiation detector, varying the volume of blood, measuring the absorbance of the patent's blood at multiple path wavelengths, and determining the blood constituent. U.S. Patent 6,222,189 to Misner et al. teaches method of measuring the concentration of a blood constituent which includes a light emitter, a light detector, applying a pressure to the extremity and taking measurements at the different pressures. The different pressures affecting the path length of the light through the extremity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

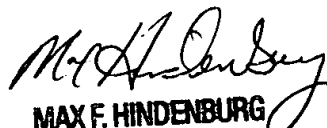
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer  
Assistant Examiner  
Art Unit 3736  
March 31, 2003



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